

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference CINJ-03-15PCT	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2004/019618	International filing date ( <i>day/month/year</i> ) 18 June 2004 (18.06.2004)	Priority date ( <i>day/month/year</i> ) 19 June 2003 (19.06.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Date of issuance of this report 19 December 2005 (19.12.2005)
	Authorized officer  Simin Baharlou  Telephone No. +41 22 338 71 30

**PATENT COOPERATION TREATY**

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 26 MAY 2005  
**PCT**  
WIPG PCT

To:  
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UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY  
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) **23 MAY 2005**

Applicant's or agent's file reference

**FOR FURTHER ACTION**  
See paragraph 2 below

CINJ-03-15PC

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/19618

18 June 2004 (18.06.2004)

19 June 2003 (19.06.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/68; C12P 19/34 and US Cl.: 435/6, 91.2

Applicant

UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
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Authorized officer

Kenneth R Horlick 

Telephone No. 703-308-0196

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/19618

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing

table(s) related to the sequence listing

b. format of material

in written format

in computer readable form

c. time of filing/furnishing

contained in international application as filed.

filed together with the international application in computer readable form.

furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/19618

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>12-30, 43-62</u>	YES
	Claims <u>1-11, 31-42, 63, 64</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-64</u>	NO
Industrial applicability (IA)	Claims <u>1-64</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claim 63 lacks novelty under PCT Article 33(2) as being anticipated by Cowser. This claim is drawn to a method comprising a quantitative real-time polymerase chain reaction system. Such a system is clearly taught in the reference in columns 25-27.

Claim 64 lacks novelty under PCT Article 33(2) as being anticipated by Wallace et al. This claim is drawn to a method using a fluorophore/biotin system. Such a system is clearly taught in the reference in Fig. 3 and column 3, lines 15-24.

Claims 1-11 and 31-42 lack novelty under PCT Article 33(2) as being anticipated by Goodfellow. These claims are drawn to methods comprising site-directed mutagenesis by PCR wherein one of the PCR primers has a mismatch which, along with a mutation to be detected in a target nucleic acid, results in introduction of a restriction endonuclease site; cleavage of said site in an amplicon by the corresponding restriction enzyme is diagnostic of the mutation. Such a method (known in the art as PIRA) is clearly taught in the reference in column 28, lines 6-25.

Claims 12-30 and 43-62 lack an inventive step under PCT Article 33(3) as being obvious over Goodfellow. These claims are drawn to applications of the basic method to well known oncogenes such as N-RAS, B-RAF, BRCA, KRAS, and EGFR, and thus no inventive step is apparent.

Claims 1-64 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.